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Johnson

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[54] **DISPOSABLE BODY ELECTRODES**

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[52] **U.S. Cl.** ..... **128/2.06 E,** 128/2.1 E, 128/417, 128/DIG. 4, 206/63.2 R

[51] **Int. Cl.** **A61b 5/04**

[58] **Field of Search** ..... 128/2.06 E, DIG. 4, 418, 128/417, 416, 404, 405, 410, 411, 2.1 E; 206/63.2 R; 204/196 B

[56] **References Cited**

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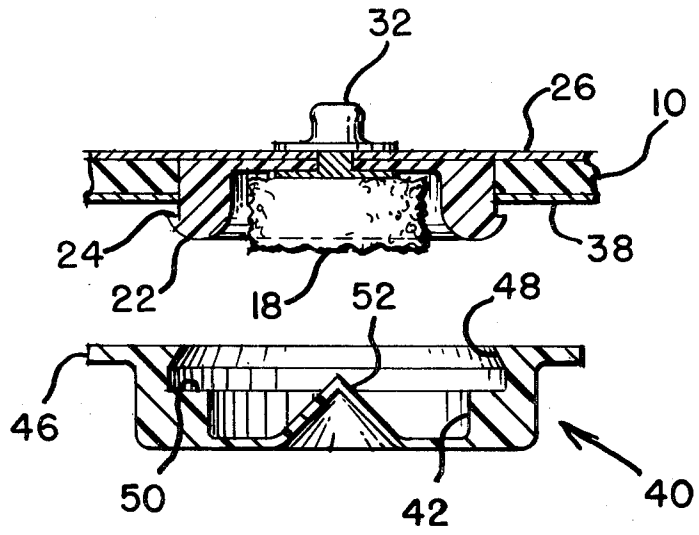
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Attorney, Agent, or Firm—Seed, Berry, Vernon & Baynham

[57] **ABSTRACT**

A single use cardiograph electrode has a self-contained electrolyte gel-impregnated pad therein set in a cup and sealed with a cap which forms an integral mechanical and frictional seal with the cup to prevent electrolyte dry-out.

4 Claims, 3 Drawing Figures



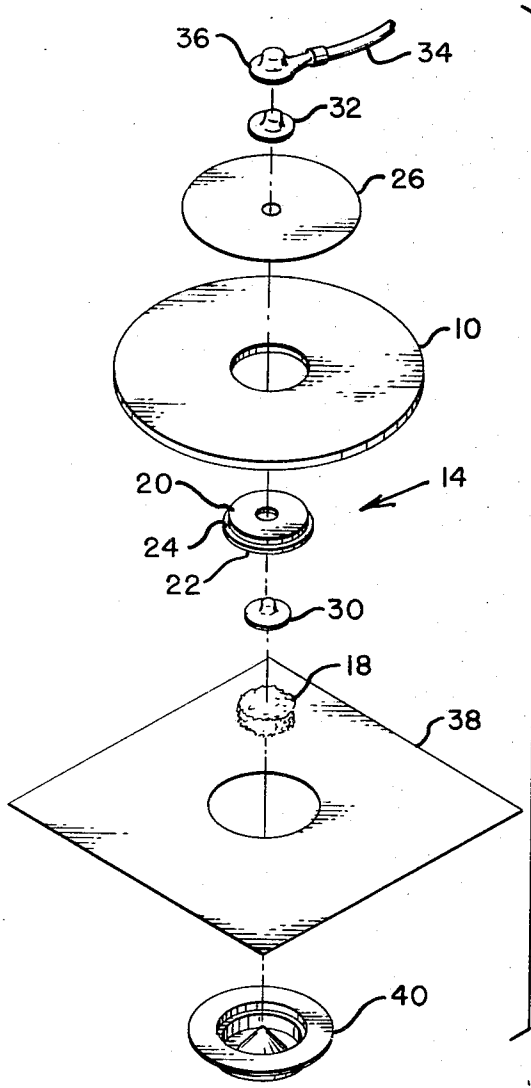


FIG. 1

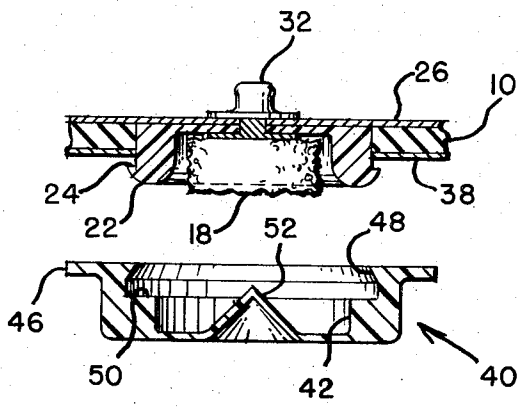


FIG. 2

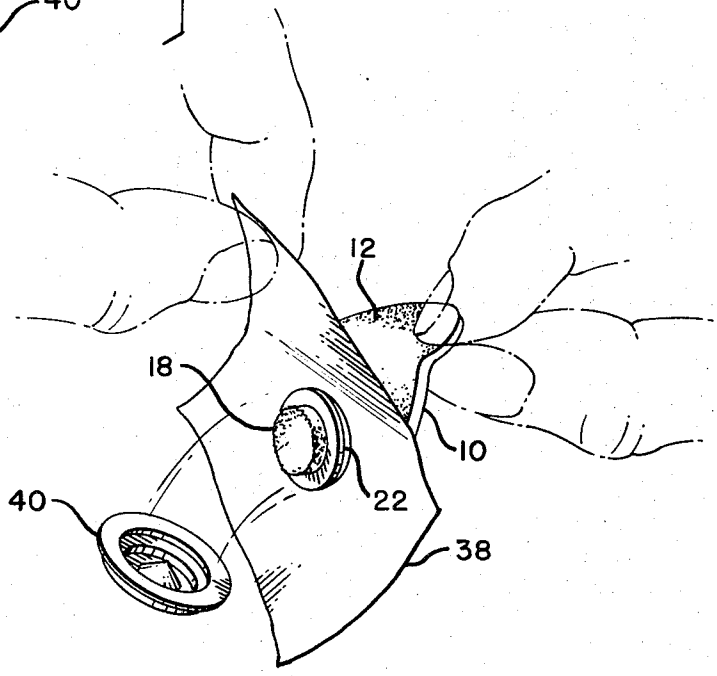


FIG. 3

DISPOSABLE BODY ELECTRODES

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a disposable body electrode having a self-contained electrolyte gel therein.

2. Prior Art Relating to the Disclosure

Disposable body electrodes for diagnostic purposes having a self-contained gel or electrolyte paste have been widely used. The problem associated with these electrodes is dry-out or evaporation of the gel prior to use of the electrodes. This is particularly the case when the gel is contained within the body of the electrode by a strippable membrane such as disclosed in U.S. Pat. Nos. 3,515,619; 3,170,459; 3,487,821; 3,590,810; 3,518,984; and 3,602,216. Hermetic sealing of the electrodes in foil packaging which is illustrated by U.S. Pat. No. 3,602,216 has been used to alleviate this problem.

SUMMARY OF THE INVENTION

This invention relates to a disposable body electrode having a self-contained electrolyte gel therein comprising: (1) a flexible, non-conductive member having an adhesive-coated surface to contact the skin surface; (2) a cup-shaped element including a cavity therein secured to the non-conductive member so that the opening of the cavity is towards the skin contacting area and the rim of the cup contacts the skin surface, the cavity designed to hold an electrolyte gel impregnated pad; (3) an electrically conductive connector disposed in the cup-shaped element; and (4) a cap over the cup-shaped element isolating the electrolyte gel from the atmosphere and preventing dry-out thereof, the cap and the cup-shaped element having means forming an integral mechanical and frictional seal therebetween.

The objects of this invention are to provide a disposable body electrode having a self-contained electrolyte gel wherein a mating cup and cap form an integral mechanical and frictional seal therebetween to prevent dry-out of the gel; to provide a disposable body electrode having a cap over a gel-impregnated pad which does not require an adhesive to hold it in place; to provide a disposable body electrode having a cup-shaped element holding a gel impregnated pad over which is disposed a replaceable cap sealing the gel-impregnated pad against contact with the atmosphere and holding the pad in place until use of the electrode.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded view of the components of the body electrode assembly of this invention;

FIG. 2 is a vertical cross-sectional view of the electrode assembly illustrating the integral seal formed between the sealing cap and cup-shaped member; and

FIG. 3 is a perspective view illustrating the manner in which peel-off of the strippable backing pops the cap loose so that the electrode is immediately available for use.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1 for an exploded view of the components of the electrode assembly, a centrally apertured, flexible foam plastic disc **10** having a pressure sensitive skin adhesive **12** coated on the underside

thereof functions to hold the remainder of the electrode assembly against the skin of the patient.

A circular cup-shaped element **14** having an outer diameter essentially the same as the diameter of the central aperture of disc **10** has an internal cavity **16** for holding an electrolyte gel or electrolyte gel-impregnated pad. The cup-shaped element is positioned in the aperture of the disc **10** so that the opening thereof is toward the skin contacting area of the electrode. The cup-shaped element has a substantially flat outer surface **20** and vertically extending side walls terminating in a rim **22.** Above the rim is an outwardly directed rib **24** extending completely around the circumference of the cup-shaped element. The rib holds the cap in place and, in cooperation with the cap to be described later, aids in effecting sealing of the self-contained electrolyte or electrolyte gel-impregnated pad within the cup. The rim **22** of the cup extends downwardly beyond the plane of the disc **10** for effective continuous contact with the skin of the patient. The cup **14** is held in place in the aperture of the disc **10** by an adhesive coated sheet plastic disc **26** covering the outer surface **20** of the cup **14** and a portion of the upper surface of disc **10** as illustrated in FIG. **2.**

An electrical conductor, suitably a male "snap" connector of conventional variety, has an inner electrically conductive disc **30** disposed in the base of the cup **14** which forms an electric connection with an outer electrically conductive disc **32.** The insulated wire **34** having a female snap connector **36** on one end thereof secured the electrode to the desired diagnostic instrument, whether a cardiograph or other suitable instrument.

A plastic foam pad **18** of polyethylene or other suitable plastic foam thoroughly impregnated with a suitable conductive electrolyte gel is disposed in the cavity of cup **14** as illustrated by FIG. **2.** The pad is of a thickness to project slightly beyond the plane of the rim **22** of the cup **14.** When the electrode assembly is affixed to the skin of the patient, the pad is slightly compressed against the skin surface forming effective and continuous electrical contact therewith.

A peel-off paper **38** having a central aperture of a diameter substantially the same as the outer diameter of cup **14** is applied to the adhesive coating of the disc **10** to protect the adhesive until the electrode is ready for use. The paper preferably extends beyond the peripheral edges of the disc **10** so that it can be readily pulled off when the electrode is ready to use.

A cap **40** is fitted over the cup **14** forming a mechanical and frictional seal therewith to hold the gel-impregnated pad **18** in place and prevent exposure of the pad to the atmosphere, thus keeping the gel moist and preventing dry-out. The integral mechanical and frictional seal between the cap and cup allows removal and replacement of the cup without resulting dry-out of the electrolyte gel-impregnated pad. Referring to FIG. **2,** the cap **40** is essentially hat-shaped in cross-section and has a base and vertical side walls **42** terminating in a rim or flange **46.** A portion of the flange **48** extends inwardly around the circumference of the cap. The side wall also has a shoulder portion **50** which contacts the rim **22** of the cup when the cap is snapped into place to form a sealing surface. The flange **48** grips the side walls of the cup **14** to form a primary frictional seal and in addition cooperatively mates with rib **24** of the cup to form a mechanical seal therebetween.

An inwardly directed dimple **52** formed in the base of the cap contacts the gel-impregnated pad and holds it in place until the electrode is ready for use. The rim or flange of the cap **46**, when snapped into place over the cup, overlaps the peel-off paper **38** so that peeling off the paper pops the cap loose from the cup, allowing immediate service of the electrode. If desired, portions of the flange **46** may be adhesively adhered to the paper **38** so that they pop off as a unit.

The electrode assembly of this invention is inexpensively and easily manufactured, reliable and does not require hermetic packaging to prevent dry-out of the self-contained electrolyte gel. The electrode is assembled by die cutting a strip of foam pad plus liner paper with a two-level die which cuts through the foam and liner paper to form a central aperture therein but only cuts through the foam pad to form a circular disc. The cup is then placed in the aperture of the disc **10** and the disc and cup adhesively bonded together with the adhesive coated plastic sheet **26.** The inner and outer portions of the snap electrical connector are then pressed into place, the gel impregnated pad inserted and the cap **40** snapped into place over the cup **14.**

The embodiments of the invention in which a particular property or privilege is claimed are defined as follows:

1. A disposable, skin-contacting body electrode having a self-contained electrolyte gel therein, comprising:

a relatively thin, flexible, non-conductive sheet material having an aperture therein and an adhesive layer thereon for contact with the skin of a subject,

a cup-shaped member, including a cavity therein, disposed in the aperture so that the opening of the cavity is toward the skin-contacting area and the rim of the cup contacts the skin surface,

a securing member bonded to the base of the cup-shaped member and the non-adhesive-coated surface of the non-conductive sheet material holding the cup-shaped member in the aperture thereof,

a male snap connector having an inner conductive disc disposed in the base of the cavity of the cup-shaped member interconnecting with an outer conductive disc disposed over the securing member having means thereon for connecting a lead wire thereto,

a strippable sheet covering only the adhesive-coated surface of the non-conductive sheet material,

an electrolyte gel-impregnated pad disposed in the cavity of the cup-shaped member in contact with the inner conductive disc and extending beyond the rim of the cup-shaped member into contact with the skin surface when the electrode is applied to the skin, and

a cap member over the pad and cup-shaped member including an inwardly extending flange around the inner circumference of the cap member which grips the side walls of the cup-shaped member to form an integral, frictional seal therebetween.

2. The body electrode of claim **1** wherein the cup-shaped member includes a rib extending around its outer circumference which mates with the flange of the cap member, the rib forming a mechanical seal with the flange of the cap member and aiding to retain the cap member over the cup-shaped member.

3. The body electrode of claim **1** wherein the cap member is hat-shaped in cross-section and wherein the inwardly extending flange is around the inner circumference of the side walls and wherein a projection extends downwardly from the base thereof, contacting the gel pad to retain it in position.

4. The body electrode of claim **1** wherein the cap member includes a rim portion overlapping the strippable sheet so that when the sheet is peeled off the non-conductive sheet material, the cap member is also removed from the cup-shaped member.

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